### **Participation Process**

## 1. What is the eligibility requirement for businesses to participate in the small business COVID-19 rapid testing pilot program?

 Eligibility: Participating Chambers of Commerce will identify a limited number of small businesses to participate. Each participating Chamber of Commerce will be responsible for establishing their own criteria and selecting small businesses to participate.

### 2. Are permission slips required to administer tests on employees?

- Permission slips are not required for individuals over 18 years old.
- Permission slips for employees under 18 years old are required. You can find a sample permission slip within <u>TEA's Public Health Orders Card</u>, which lays out all the basic information needed to register an individual for a test.

## 3. Do we have to use the tests in a specific way or on specific populations?

- It is recommended that small businesses conduct testing in two ways:
  - Targeted Testing
    - Test administrators may conduct testing on employees who present symptoms of COVID-19 while at work
    - All test administrators must receive a parental authorization form for any individual under 18 years of age to be tested

#### Screening

- Small businesses may conduct testing on all employees as tests are available or on specific groups of employees who may be more at risk.
- Each small business will, however, determine the testing strategy that will meet the needs of their business within the following limitations:
  - All testing in small businesses as a part of this program will be conducted on a voluntary basis;
  - Testing shall not be a condition of employment;
  - Tests will only be conducted on employees of the business;
  - All individuals conducting the testing will have complied with the training requirements;
  - Individuals tested will not be charged for the test; and
  - Federal law requires that all results of the tests will be reported through the app.txrapidtest.org application.

#### 4. Can we require an employee to take the BinaxNow test?

 Businesses cannot mandate the use of the Abbott BinaxNow Ag Card Tests on their employees.

### 5. Can relatives of employees be tested?

You must be an employee of the small business to be eligible to receive testing. For every positive case, a whole household is potentially affected. Please refer those individuals to the TDEM and DSHS COVID-19 Test Collection Sites Map at <a href="http://www.covidtest.tdem.texas.gov">http://www.covidtest.tdem.texas.gov</a>.

### 6. Can we charge employees to take this test?

• No. These tests are being provided free of charge from the federal government, and businesses cannot charge for administering the tests.

### 7. How long is this testing program slated to run?

 The program duration will be dependent on the number of BinaxNow test kits that are ultimately provided by our federal partners and the level of participation from businesses.

### 8. Is the Businesses responsible for contact tracing of the tests administered?

 Businesses should work with their local health authority to support contact tracing requirements for individuals who test positive.

### What kind of test is this?

## 1. What type of rapid antigen tests will be provided by the state, who is the manufacturer?

- The state is using <u>Abbott BinaxNow Ag Card Tests</u>. These credit card-sized rapid tests can potentially be largely self-administered through a nasal swab and deliver results in 15 minutes.
- The ABBOTT BinaxNow Antigen Immunoassay Test detects the presence of a specific viral antigen, which implies current viral infection. This test kit is a screening tool that identifies the presence of viral antigens (SARS-CoV-2) in the body.

### 2. What are the differences between an antigen, PCR and antibody test?

- The antigen tests identify the virus by detecting the proteins from the virus.
- The molecular test (RT-PCR) detects the virus's genetic material to see if you have an active coronavirus infection.
- An antibody test looks for antibodies that are made by your immune system in response to a threat.

# 3. Does a Chamber of Commerce or business need to obtain their own Clinical Laboratory Improvement Amendment (CLIA) authority to administer the tests?

The Texas Division of Emergency Management (TDEM) has obtained a CLIA waiver (#45D2193699) which allows for testing at multiple locations including businesses across the state. TDEM's CLIA information, along with the provider of record will automatically populate in the test registration system and should not have to be manually entered by test administrators.

#### 4. Is there an expiration date or shelf life for the BinaxNow Test?

 Tests have an expiration date that is printed on the outside of each box of test kits. The test kits have a six-month shelf life if stored between thirtysix (36) and eighty-six (86) degrees Fahrenheit.

### 5. How accurate is this type of test?

- Abbott evaluated its test in 102 patients who had shown COVID-19 symptoms for less than 7 days and compared the results with a PCR test. This analysis showed that BinaxNOW has a:
  - sensitivity (true positive rate) of 97.1%
  - o specificity (true negative rate) of 98.5%.

# 6. Could this rapid test be used to shorten the 14-day quarantine period, or does the 14-day quarantine with close contact still stand as outlined by CDC regardless of the result of the test?

A negative test cannot be used to shorten the stay-at-home period for an asymptomatic close contact, because that stay-at-home period covers the incubation period of the virus. During the entire 14-day quarantine period, an individual could potentially test negative and not have symptoms but still be incubating COVID-19.

### **Training**

### 1. Do test administrators have to be medically trained?

 No, individual test administrators must complete the required training and report all results through txrapidtest.org.

### 2. How do I obtain certification training?

- Login and register for www.preparingtexas.org
- In preparingtexas.org registration, in the space for "Agency or Organization Name," put the Chamber of Commerce or Business Name
- Complete training course Binax-300 for small businesses Course on preparingtexas.org.

## 3. I registered for the BinaxNow Training, but the links are not active for the course. How do I access the course?

 Once you are registered for the course, click on the home button at the top left of the page. On the Home screen, you will see a list of "Registered Online Courses. Your BinaxNow course should be listed and you will click on the link "Go To" beside the BinaxNow course to access the training.

#### 4. Who is the Test Coordinator?

 Test Coordinator: Each participating chamber of commerce will identify one Test Coordinator to coordinate the testing at the small businesses and serve as the point of contact for TDEM.

### 5. Who will be administering the tests?

- Test Administrator: Only a certified test administrator is authorized to conduct the rapid ABBOTT - BinaxNow test
- Test administrators will be determined at the small business. A test administrator may be any individual identified by the business who completes the required training and submits all testing results as required by state and federal law
- You will need to identify the testing administrators to the chamber of commerce. The individual(s) identified by businesses will need to complete the training course Binax-300 on www.preparingtexas.org. Upon successful completion, the test administrator's information will be automatically loaded into the reporting system within one hour, and they will be ready to begin testing.

### 6. Do we need to have a doctor's guidance or permission to perform these tests?

 Dr. Alex Lazar (https://faculty.mdanderson.org/profiles/alexander\_lazar.html) has agreed to serve as the provider of record for the BinaxNow tests in the Chamber of Commerce Program. This information will be included in the data reported to DSHS on each individual's information and test results that are entered into the https://app.txrapidtest.org/ portal by test administrators.

## 7. Can I contract out with a 3rd party provider (clinic, outside vendor) to perform our testing program?

 Each business can determine the testing logistics that make the most sense for them; however, third party providers are not allowed to collect a fee or copay for performing these services.

#### 8. How many tests can be administered at once?

 This will largely be dependent upon the availability of test administrators identified by the business and the testing logistics put in place at the local level.

 Depending on the number of employees being tested, these tests can largely be self-administered for employees. Tests must be reviewed and logged into the system within 15 minutes of administering the test.

### **Testing**

### 1. Can employees enter the required information before they come in for a test?

- Yes. Have employees over 18 years of age go to: https://register.txrapidtest.org/. They will need to fill out the information required, and press submit. A QR code will be created that contains the information necessary to register. They may print out the QR Code,or take a picture on their phone to bring to the testing location.
- Legal guardians of employees under 18 years of age may also use the QR Code generator for their children, but they must also provide a signed permission slip.

## 2. If a test administrator who successfully completed the training does not have a password for app.txrapidtest.org how can they get one?

Select the "forgot password" link and follow the instructions.

### 3. How long does the test take?

After the test is obtained using a sterile swab, the <u>ABBOTT - BinaxNow</u>
 Card takes 15 minutes to return a result

## 4. How long after adding the reagent to the test card can I wait to insert the swab and conduct the test?

 Abbott Labs has indicated that the swab must be inserted into the card within 3 minutes of adding the reagent.

#### 5. If I test (+) positive, do I have COVID-19?

- Presumptive Test: This test is only an indicator of the presence of the COVID-19 virus
- A formal medical evaluation and certified laboratory verification would be necessary to indicate a confirmed infection
- Presumptive-positive results also do not rule out bacterial infection or coinfection not related to COVID-19. Please refer to the consultation form provided by Abbott.

#### 6. Does this test identify the common cold or strep throat?

No: This is a specific test for the COVID-19 virus SARS-CoV2

#### 7. Can the card show a presumptive-positive before the time is up?

 The result can ONLY be evaluated after 15-minutes and NO LATER Than 30-minutes after collection to determine the result

### 8. Can a faint line indicate a presumptive positive result?

- Yes: Faint but still readable, results are considered to be conclusive results
  positive or negative
- Inconclusive results will include the blue control line not changing, only the sample line is displayed, or no line displayed at all
- The test is to be re-taken and the test administrator notified of the inconclusive result

#### 9. What do I do if the test card is defective?

- No adhesive strip on the right side of the card Scan the card, enter no information, press 4 at the top of the screen, select "Test Not Performed" and submit. Throw the card away, and use a new card
- Plastic well for the reagent is absent- Scan the card, enter no information, press 4 at the top of the screen, select "Test Not Performed" and submit. Throw the card away, and use a new card
- The test strip itself is displaced- Scan the card, enter no information, press 4 at the top of the screen, select "Test Not Performed" and submit. Throw the card away, and use a new card
- If a significant number of cards are defective (more than 5), contact Abbott Labs Technical Support at 1-800-257-9525

### 10. What do I do if I forget to put the reagent solution into the card before the nasal swab?

 Scan the card, under results enter "Invalid", and press submit. Throw the swab and card away and begin the test again with a new card and swab.
 You will need to re-enter the information for the individual to be tested.

#### 11. What do I do if the control line never turns pink/purple?

 Scan the card, under results enter "Invalid", and press submit. Throw the swab and card away and begin the test again with a new card and swab.
 You will need to re-enter the information for the individual to be tested.

### 12. Who is liable if an employee is injured by the testing?

Consult your business' legal counsel.

## 13. Are the used test kits and used PPE considered medical waste for disposal?

- The used Test Kits are considered Medical Waste and must be disposed of according to TCEQ guidelines which may be found here: <a href="https://tdem.texas.gov/chambertesting/">https://tdem.texas.gov/chambertesting/</a>.
- PPE used while handling and administering the rapid COVID test kits are not considered medical waste.

#### 14. Can these tests be used on asymptomatic individuals?

• Yes. The Center for Medicare & Medicaid Studies will allow testing on asymptomatic individuals during the public health crisis.

# 15. Do N-95 masks need to be fit tested? If a N95 mask does not go through fit testing does that make it less effective than a surgical mask?

- OSHA respiratory protection standards <u>require initial and thereafter</u>, <u>annual fit-testing of N95</u> or any other tight-fitting respirators for staff who may be required to it. During COVID-19 public health emergency, OSHA has temporarily applied enforcement discretion for annual-fit testing requirement, as long as employers have made good-faith efforts to comply with standards and steps outlined in April 8, 2020 memoranda (<a href="https://www.osha.gov/memos/2020-04-08/expanded-temporary-enforcement-guidance-respiratory-protection-fit-testing-n95">https://www.osha.gov/memos/2020-04-08/expanded-temporary-enforcement-guidance-respiratory-protection-fit-testing-n95</a>). This enforcement discretion is also applicable when an employer switches to an equivalent-fitting make/model/size/style of N95 or another tight-fitting respirator without performing an initial fit test.
- As per <u>CDC/NIOSH</u>, "Under serious outbreak conditions in which respirator supplies are severely limited, however, you may not have the opportunity to be fit tested on a respirator before you need to use it. While this is not ideal, in this scenario, you should work with your employer to choose the respirator that fits you best, as, even without fit testing, a respirator will provide better protection than a facemask or using no respirator at all."

### Reporting

#### 1. How are test results shared with the individual being tested?

- As part of the test registration process, the individual or their guardian's phone number and email address are entered into app.txrapidtest.org.
   Once the test results are put in the system by the test administrator, a text message and email are autogenerated to notify the individual.
- There is no auto-generated report to let the business know who and when someone tested positive. Test administrators will also have access to this information as they are inputting the test results and should work with their business to determine if an additional process is needed.

#### 2. What happens when someone tests positive?

- This is a process that will be determined at the local level. It is recommended that businesses follow public health guidance from DSHS and the CDC and that any positive case be removed and seek a PCR test to confirm the positive result.
- Businesses should also contact the local health department to provide information on any individual who tests positive.

## 3. If an employee receives a positive test result, should we direct them to get a PCR (molecular) lab-based test?

 Yes, this is a presumptive positive test and is a mechanism for businesses to immediately identify presumptive positive cases. People receiving a positive test should consider obtaining a more formal PCR (molecular) labbased test.

### 4. How is my personal information used?

- All personal Health information collected in registration and results will be handled under local, state and national privacy rules
- Individual Level registration and results information in the registration application will only be shared with the Department of State Health Services as required by Law.
- Aggregate level information without personally identifiable information may be shared with businesses and the public.

### 5. How is the reporting system accessed?

- Login and register for www.preparingtexas.org.
- Complete the Binax-300 Course on preparingtexas.org.
- Individuals who successfully complete the Binax-300 course receive login information for the testing application at https://app.txrapidtest.org. The registration process may take up to one hour before it is active. You will need this APP to report the results from each test.

#### Results

# 1. Does the test information get shared with the local health department and DSHS or do businesses need to report these cases to the appropriate authority?

- TDEM, through our partner agency, Southwest Texas Regional Advisory Council (STRAC), will report employee registration of individuals to be tested, the entering of test results, and the report of test results to the Texas Department of State Health Services
- As required by law, all results negative, positive, and inconclusive from testing shall be reported daily to the Department of State Health Services DSHS through the provided test portal system *Texas Rapid Test app* -<a href="https://app.txrapidtest.org/">https://app.txrapidtest.org/</a>



### **Equipment**

### 1. What will we use to register/test/input information related to testing?

- Every test administrator will need an iPhone, iPad, or Android device to scan driver's license information, ABBOTT - Binax Now Test QR Code, and/or manually enter additional personal information regarding the individual to be tested.
- This is a web-based portal and not an application that will need to be downloaded on a device.

### **Ordering**

### 1. What type of storage capacity is needed to accommodate these tests?

There are 40 tests and one (1) reagent solution in a shoebox-sized box.
 The Binax Now test kits must be stored below 86 degrees Fahrenheit at all times in order to maintain integrity.

### 2. Will we receive PPE to conduct these tests?

 TDEM will provide PPE for test administration in the form of surgical masks and N-95 masks.

#### 3. How do I order more test kits or PPE?

 Any need for more test kits or Personal Protective Equipment (PPE) by a test administrator used only for testing purposes should be routed to your chamber test coordinator.